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| 09/943,380      | 08/30/2001  | S. Grant Mulholland  | 10303-2 US          | 7757             |

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EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/943,380

Applicant(s)

MULHOLLAND ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-64 and 73-79 is/are pending in the application.
- 4a) Of the above claim(s) 65-72 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 61-64 and 76-79 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 8, 10, 11, 13-26, 28-34, 39-42, 44-53, 55-60, 73-75 is/are rejected.
- 7) ☐ Claim(s) 3-6, 9, 12, 27, 35-38, 43 and 54 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 2, 8, 10, 11, 13-15, 18-21, 23, 32-34, 39-42, 44-48, 50 and 58; are rejected under 35 U.S.C. 102(b) as being anticipated by D'Augustine et al., 6,416,779.

As to claims 1 and 33, D'Augustine discloses a urethral suppository (col. 9, line 63) for insertion into a female urethra comprising a non-meltable base member (47); a non-meltable reinforcement (44) having a length, said length having a first end (proximal portion of 44) and a second end (distal portion of 44), said first end attached to said base member and projecting from said base member (see Figure 6); and a meltable portion (medicine, col. 15, line 24) formed around a portion of said length of said reinforcement, said meltable portion having a diameter which tapers from said second end toward said first end (see fig. 6.)

As to claims 2 and 34, the base member (47) is shaped for handling.

As to claims 10 and 41, the reinforcement (44) projects substantially perpendicular from said base member (47.)

As to claims 11 and 42, the reinforcement (44) comprises a rod.

As to claim 15, the second end of the reinforcement (44) extends outside the meltable portion (see fig. 6.)

As to claims 13 and 44, the reinforcement (44) is formed from rubber (see col. 15, line 19.)

As to claim 14, the second end of the reinforcement (44) is contained entirely within the meltable portion (medicine). (Examiner notes that Applicant has not defined where the "second end" starts, and thus Examiner interprets the "second end" in claim 14 to include part of 44 within the medicine portion.)

As to claims 18-21, 45-48, the reinforcement (44) comprises a restraint.

Also, as to claim 61, a method for delivering therapeutic agents to the female urinary tract using the suppository is disclosed (see column 5, line 20, and column 7, line 60.)

As to claims 8, 40, the base is comprised of polymer (col. 15, lines line 21.)

As to claims 23, 50, the meltable portion comprises antifungals (see col. 20, line 39.)

As to claim 32, 58, the meltable portion is capable of melting within about 2 minutes to about 60 minutes (see medicaments in col. 20, lines 39-43.)

As to claim 39, the base member fits within the labia minora of a patient.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 16, 17, 24, 25, 30, 31, 51, 52, 57, 59, 60, and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Augustine et al., 6,416,779.

D'Augustine discloses the invention substantially as claimed (see above). More specifically, D'Augustine teaches that the suppository is for treatment of various medical conditions in various body parts (see col. 5, lines 12-22.) However, D'Augustine does not teach the dimensions of the suppository as claimed in claims 16, 17, 24, 25, 30, 31, 51, 52, 57, 59, 60 and 73-75.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In this case, D'Augustine teaches the general conditions of the claims (see above with under the 102 rejections). Providing the claimed dimensions as would be necessary to fit inside the urethra, vagina, rectum, pharynx, or other body parts of patients provides optimum or workable ranges and thus involves only routine skill in the art under *In re Aller*.

3. Claims 22 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Augustine et al., 6,416,779, in view of Jackson et al., 4,542,020.

D'Augustine et al. discloses the invention substantially as claimed (see above), except for the meltable portion comprising cellulose.

Jackson also teaches a suppository that melts for delivery of medication (column 62-65.) The suppository melts when placed in the patient (column 3, lines 24-28.) Jackson further teaches that the suppository comprises cellulose (column 3, lines 5-10) in order to provide for uniform distribution of the medication (col. 2, lines 6-12.)

It would have been obvious to provide cellulose in the meltable portion of the D'Augustine suppository in order to provide the advantage of uniform distribution of medication as taught by Jackson.

4. Claims 26, 28, 29, 53, 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Augustine, 6,416,779 Sushko, 1,767,785.

D'Augustine discloses the invention substantially as claimed (see above), except for helical grooves being formed in the meltable portion.

Sushko discloses a urethral suppository. Sushko further discloses helical grooves (11) to retain the suppository inside the urethra (column 2, lines 5, and 54-56.) It would have been obvious to provide helical grooves in the D'Augustine urethral suppository to provide the advantage of retaining the suppository inside the urethra as would be desirable for delivering medication to the urethra, as taught by Sushko.

***Allowable Subject Matter***

5. Claims 3-6, 9, 12, 27, 35-38, 43 and 54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Claims 61-64 and 76-79 are allowed.

***Response to Arguments***

Applicant's arguments with respect to the above rejected claims have been considered but are not persuasive.

Applicant argues that D'Augustine does not teach insertion of the suppository into the urethra, but rather teaches insertion into the vagina and that drug delivery to the urethra is through the circulatory system. This argument is not persuasive as to the device claims because a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). In this case, the device is capable of performing the intended use, including insertion into the

urethra. (As to the method claims, Applicant's arguments are moot because the rejections of the method claims have been withdrawn.)

Applicant also argues that loop (47) is not a base member and that the dictionary definition of base member is "the bottom of something considered as its support". Applicant's argument is not persuasive because loop (47) is at the bottom of, for example, element (44) and is considered its support (see figure 6).

Applicant also argues that loop (47) in the D'Augustine device does not function as a base and cannot function to limit the insertion of the device into the urethra. Applicant argues that loop (47) merely serves as an attachment structure for string (48) and cannot interact with any body structure to limit insertion of the device into a body channel. This argument is not persuasive because Applicant does not claim that the base interacts with a body structure to limit insertion of the device into a body channel. Applicant does not claim how the base limits insertion nor does Applicant claim structural limitations that would distinguish Applicant's claims over the D'Augustine device.

Applicant also argues that the D'Augustine vaginal device is not a suppository because the body of the D'Augustine vaginal device is not meltable but is principally composed of materials which do not melt (i.e., the porous foam portion (43)). This argument is not persuasive because the D'Augustine device is not only disclosed by D'Augustine as a suppository (see col. 9, line 63) having medication (i.e., the meltable portion, col. 9, lines 62-63), but Applicant's description of Applicant's suppository also has a non-meltable portion. Thus, the fact that the D'Augustine device has a non-



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meltable portion does not preclude it from being a suppository. Applicant has not claimed structural elements that would distinguish Applicant's invention from the D'Augustine device.

Applicant also argues that non-porous tube (44) of the D'Augustine device is not a "reinforcement" and that the function of the reinforcement of the claimed invention is to make the suppository stiffer and to hold the meltable portion in place as it dissolves in the urethra. This argument is not persuasive because nothing in the specification defines a "reinforcement" such that it would preclude the D'Augustine tube (44) from being considered a reinforcement. Moreover, the D'Augustine tube (44) does make the suppository stiffer and hold the meltable portion in place as it dissolves.

Applicant's arguments with respect to the method claims are moot because the rejections of the method claims are now withdrawn.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822.

The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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08/27/05